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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

PULSE HEALTH LLC, an Oregon limited liability company, Plaintiff, v. AKERS BIOSCIENCES, INC., a New Jersey corporation, Defendant.	CASE NO.: _____ **COMPLAINT** **(Lanham Act (15 U.S.C. 1125(a)); Unlawful Trade Practices (ORS 646.608); Breach of Contract)** **DEMAND FOR JURY TRIAL**

Plaintiff Pulse Health LLC ("Pulse") for its Complaint against Akers Biosciences, Inc. ("ABI"), alleges as follows:

THE PARTIES

1. Plaintiff Pulse is an Oregon limited liability company with a principal place of business at Two Centerpointe Drive, Suite 500, Lake Oswego, Oregon, 97035. Its owners and members are citizens of Oregon, California, Texas and Florida. None of its owners or members are citizens of New Jersey.

2. Defendant ABI is a New Jersey corporation with a principal place of business at 201 Grove Road, Thorofare, New Jersey, 08086.

JURISDICTION AND VENUE

3. Federal question subject matter jurisdiction exists in this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and (b). Supplemental jurisdiction of Plaintiff Pulse's state law claim(s) exists pursuant 28 U.S.C. § to 1367(a).

4. ABI is subject to personal jurisdiction in this District and venue is therefore also proper pursuant to 28 U.S.C. § 1391(b)(1). In addition, a substantial part of the events at issue occurred in this District and the Portland division and a substantial part of the property at issue exists here and in the Portland division. Venue is therefore also proper pursuant to 28 U.S.C. 1391(b)(2) and Local Rule 3-2(3).

5. Plaintiff Pulse entered into several contracts with Defendant API, including the April 8, 2011 Assignment, License and Settlement Agreement ("Settlement Agreement") at issue in this action. The Settlement Agreement and its predecessors were all negotiated by Pulse from its offices in this District and ABI's officers visited Pulse's offices in this District on numerous occasions in order to consult with Pulse regarding the development and testing of the Assigned Technology and Pulse Technology at issue in the Settlement Agreement. At least some of the

testing for the Assigned Technology and Pulse Technology was performed with Portland, Oregon residents.

6. ABI understood and agreed that Pulse would exploit its exclusive and ownership rights to the Assigned Technology and Pulse Technology under the Settlement Agreement in this District. ABI further knows that Pulse has exploited such rights in this District from 2011 through the current date.

7. ABI's breaches, misappropriation and false advertising set forth in this Complaint were directed against both Pulse and the residents of the state of Oregon. ABI knew that its breaches, misappropriation and false advertising would damage Pulse's exclusive rights and competitive product, and mislead the consumers of Oregon and other states.

STATEMENT OF FACTS

The TD Agreement

8. On or about September 14, 2007, Pulse and ABI entered into a Technology and Development Agreement ("TD Agreement"), a true and correct copy of which is attached hereto as Exhibit 1.

9. As set forth in the TD Agreement, Pulse had invented a hand-held computer system that a lay person or health practitioner could interface with to measure certain health markers, such as aldehyde molecules, through a simple breath test, as opposed to a blood or urine test. Exhibit 1, p. 1, Introductory ¶ 3, Ex. B. Generally stated, the presence of aldehydes are indicative of "oxidative stress" or the inability of a person's body to manage or detoxify reactive oxygen species. Oxidative stress results when the body is unable to properly manage the generation of "free radicals," or molecules with unpaired electrons. Oxidative stress and the inability to manage free radicals are implicated in many chronic health issues, including cancer,

heart and arthritic diseases. Pulse coined its product "FRED," an acronym for "Free Radical Enzymatic Device."

10. ABI, on the other hand, had invented a test kit for a Blood Alcohol Test in which a person could blow into a tube or "reaction cell" that contained chemical reagents. The chemical reagents would react and change color based upon their interaction with alcohol present in breath condensate. *Id.*, ¶ 2, Ex. A. ABI further claimed that it had invented tubes containing chemical reagents that captured a product of "free radical metabolism, such as aldehydes, MDA or peroxides, and react such substances with a compound, producing a color…" *Id.* Similar to measuring alcohol in its Blood Alcohol Test, ABI was purportedly measuring the amount of aldehydes resulting from the chemical reaction between the chemical reagents and a person's breath condensate.

11. The purpose of the TD Agreement was for ABI to design and develop "New Versions" of its existing free radical test product in order for it be used in combination with Pulse's hand-held FRED product. Exhibit 1, p. 1, Introductory ¶ 5. Pulse was to pay for development of the New Versions and own all intellectual property associated therewith, and maintained all ownership of its own FRED intellectual property. *Id.*, ¶¶ 1(a), (b); 7. If the New Versions were successfully developed and tested, ABI would manufacture the New Versions for Pulse to sell with its FRED product, and the parties entered into a separate Supply and Manufacturing Agreement ("Supply Agreement) to reflect those terms. *Id.*, ¶¶ 1(b); 2.

The TT Agreement

12. The TD Agreement and its companion Supply Agreement were terminated in a December 31, 2008 Technology Transfer Agreement ("TT Agreement"), a true and correct excerpted copy of which is attached hereto as Exhibit 2.

13. Under the TT Agreement, ABI assigned all intellectual property rights of any kind in the "Assigned Technology" to Pulse. Exhibit 2, ¶¶ 1.5, 2.1, Schedule 1.5. The "Assigned Technology" included all technology related in any way to non-invasive exhaled breath testing, excluding only an ABI Retained Patent which was exclusively licensed to Pulse. The Assigned Technology included, but was not limited to, everything ABI had created related to its "Free Radical Breath Condensate" technology, including all chemical reagents, breath tubes and reaction cells, as well as all testing for monitoring degrees of oxidative stress. *Id.* In addition, ABI agreed to complete research, development and testing for the "Free Radical Technology" including, among other things, "To evaluate the impact of individual aldehydes concentration levels." *Id.*, ¶ 2.5. Pulse agreed to pay a Transfer Fee for the above technology of $3,000,000 in periodic payments through June of 2010. *Id.*, ¶ 4.

14. The TT Agreement also provided ABI with a license back to use the Assigned Technology in the "ABI Field," which was limited to the fields of ABI's Ketone Check product (a breathalyzer tube to detect ketones in diabetic patients), Pulmo Health Check product (a breathalyzer tube to detect interleukins for the diagnosis of lung cancer) and BreathScan product (a breathalyzer tube to detect alcohol). Exhibit 2, ¶ 3.2, Schedule 1.1. In addition, the parties amended the Supply Agreement to provide for ABI's potential manufacture and sale of the "FRED Aldehyde Assay Tubes" set forth in Schedule B. *Id.*, ¶ 5.2, (a) and (b). These tubes contained the Assigned Technology that ABI had assigned to Pulse in the TT Agreement.

15. The TT Agreement was amended but the parties subsequently terminated all prior agreements between each other and entered into the April 8, 2011 Settlement Agreement at issue in this action.

The Settlement Agreement

16. Despite numerous representations to the contrary, ABI could not develop Free Radical Technology that successfully tested for the accurate measurement of aldehydes in breath condensate. The chemical reagents developed by ABI simply did not work. For example, Pulse determined in its testing laboratory that the chemical reagents did not in any way detect aldehydes and that the change in color in the tube was created by humidified air (i.e. water), alone. After working with ABI for over three years, Pulse requested to part ways with ABI and the parties entered into the comprehensive Settlement Agreement, a true and correct copy of which is attached hereto as Exhibit 3.

17. Under the Settlement Agreement, Pulse assigned and transferred the Assigned Technology set forth in Schedule 1.5 of the TT Agreement (Exhibit 2) back to ABI and ABI waived the remainder of Pulse's $3,000,000 payment. Exhibit 3, ¶¶ 1.5, 2.1. ABI granted Pulse an *exclusive and perpetual* license to use the Assigned Technology in the field of Aldehyde Tests, which included any testing for oxidative stress. *Id.*, ¶¶ 1.3, 3.4. ABI specifically excluded from the field of Aldehyde Tests the "ABI Field" of Alcohol, Ketone and Pulmo breath testing identified in paragraph 13. *Id.*

18. ABI further agreed that it had *no rights* with respect to Pulse's Technology for its hand-held FRED device, then referred to as Revelar, including any designs, developments or know how. *Id.*, ¶¶ 1.7, 5.

ABI's Breaches, Misappropriation and False Advertising

19. In approximately May of 2012, ABI offered for sale a "Vivo" hand-held system that it claimed measured oxidative stress and free radical damage through disposable tubes. A true and correct copy of ABI's advertising for its Vivo system is attached hereto as Exhibit 4.

ABI claimed that its Vivo system measured hydrogen peroxide and superoxide as biomarkers of free radical damage and oxidative stress. *Id.*

20. Pulse reviewed the Vivo system on ABI's website and determined that it was at least a copy of the Pulse Technology developed for the FRED/Revelar system. Pulse advised several of its former agents and consultants who were working with ABI in the development and sale of its Vivo system of their confidentiality and contractual breaches, and demanded that they immediately cease and desist such activities. ABI subsequently removed the Vivo system from the marketplace.

21. In late December 2015, Pulse became aware that ABI was offering an "OxiChek" product for sale at a trade show in Las Vegas. The OxiChek product uses a "BreathScan Lync" hand-held reader device in which a chemical reagent tube is inserted therein after a person has exhaled breath into it. The BreathScan device purportedly measures free radicals such as superoxides, hydrogen peroxide and aldehydes, and sends the results to the BreathScan software application that is downloaded on a person's mobile phone or computer. The BreathScan software then purportedly displays oxidative stress/free radical results in three different zones dictated by color codes. A true and correct copy of the OxiChek advertising materials offered by ABI at the trade show are attached hereto as Exhibit 5.

22. After reviewing the advertising materials, Pulse sent ABI a cease and desist letter on March 1, 2016, a true and correct copy of which is attached hereto as Exhibit 6. Pulse complained of two things: (1) that ABI was advertising and selling a product that required FDA approval, which it did not have; and (2) that ABI may be using the Assigned Technology and Pulse Technology in breach of the parties' Settlement Agreement. *Id.* On the latter point, Pulse requested ABI's technical materials which would show the composition of its chemical reagents.

23. In response to Pulse's cease and desist letter, ABI refused to remove its product from the market and also refused to provide any information concerning its OxiChek product, including a sample thereof. ABI apparently did change its advertising to remove any reference to testing aldehydes and now referred to its OxiChek product as a "general wellness product" that "does not require FDA clearance." A true and correct copy of such advertising is available on ABI's website and is attached hereto as Exhibit 7. On information and belief, ABI did not make any changes to the OxiChek product, including its chemical reagent, from December 2015 through the present.

24. In late July, 2016, Pulse was able to obtain a sample of the OxiChek product from an ABI distributor and analyze and operate it in detail. Pulse's analysis of the OxiChek shows that it is a copy of the Assigned Technology and Pulse Technology in several respects. With respect to the Assigned Technology, at least the chemistry for the OxiChek and the Assigned Technology reagents are the same. ABI knew from 2008-2011 that these chemical reagents could not detect aldehydes (or superoxides or hydrogen peroxide for that matter) because their change in color resulted from humidified air as opposed to the presence of these types of molecules.

25. With respect to the Pulse Technology, the circuit boards for the OxiChek product have a similar layout and the same optical chamber, LED, diodes, switches and gates as the original FRED/Revelar device developed by Pulse.

FIRST CLAIM FOR RELIEF
(False Advertising under Lanham Act, 15 U.S.C. 1125(a))

26. Pulse incorporates by reference and re-alleges paragraphs 1-25 as if fully set forth herein.

27. ABI's statements in its consumer advertising that the OxiChek product "Provides quantitative level of oxidative stress / free radicals" and that it "Measures the abundant free radicals – superoxides and hydrogen peroxide," are false. The OxiChek product uses the same FRED/Revelar chemistry that ABI knows does not detect or measure the presence of superoxides or hydrogen peroxide and therefore cannot provide quantitative levels of oxidative stress or free radicals. ABI's advertising is distributed in interstate commerce.

28. ABI's misstatements are the most material representations it makes in its OxiChek advertising and deceives the consuming public in Oregon and elsewhere in a material way.

29. Pulse has been damaged by ABI's false advertising in an amount not less than $500,000.

30. Pulse is entitled to a permanent injunction for ABI's false advertising under 15 U.S.C. § 1116.

SECOND CLAIM FOR RELIEF
(Unlawful Trade Practices, ORS 646.608)

31. Pulse incorporates by reference and re-alleges paragraphs 1-30 as if fully set forth herein.

32. ABI has made willful false statements about the qualities of its goods in its advertising to Oregon consumers. ABI states that the OxiChek product "provides quantitative level of oxidative stress / free radicals" and that it "Measures the abundant free radicals – superoxides and hydrogen peroxide." The OxiChek product uses the same chemistry as the FRED/Revelar chemistry that ABI knows does not accurately detect or measure the presence of superoxides or hydrogen peroxide and therefore cannot provide quantitative levels of oxidative stress or free radicals.

33. Pulse has suffered ascertainable damages in an amount not less than $500,000.

34. Pulse is entitled to injunctive relief pursuant to ORS § 646.638(1).

THIRD CLAIM FOR RELIEF
(Breach of Contract)

35. Pulse incorporates by reference and re-alleges paragraphs 1-34 as if fully set forth herein.

36. The Settlement Agreement is a valid and existing contract that was supported by consideration. Pulse has fully performed any all obligations thereunder, including the transfer of the Assigned Technology to ABI.

37. ABI has breached the Settlement Agreement by using both the Assigned Technology in the Aldehydes Field and by using the Pulse Technology of the FRED/Revelar device.

38. Pulse had been damaged by ABI's conduct in an amount according to proof but not less than $500,000.

PRAYER FOR RELIEF

Pulse prays as follows:

a) For all damages, including treble damages, as well as ABI's profits resulting from ABI's false advertising;

b) For attorneys' fees for ABI's false advertising because this is an exceptional case;

c) For damages and attorneys' fees for ABI's unfair trade practices;

d) For an injunction prohibiting the manufacture, use and sale of ABI's OxiChek product;

e) For an injunction prohibiting ABI's false advertising;

f) For all damages resulting from ABI's breach of contract;

g) For costs of suit; and

h) For such other relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made by Plaintiff Pulse Health LLC, by and through its counsel of record, for trial by jury in the above-entitled action pursuant to Fed. R. Civ. P. 38(b).

DATED September 30, 2016.

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